JAN 14 2005 K043252 (pg 1 of 2)

510(K) SUMMARY
CABLING SYSTEM TROCHANTERIC HOOK

SUBMITTER'S NAME:	Smith & Nephew, Inc., Orthopaedic Division
SUBMITTER'S ADDRESS:	1450 Brooks Road, Memphis, TN 38116
SUBMITTER'S TELEPHONE NUMBER:	901-399-6670
CONTACT PERSON:	John Reabe
DATE SUMMARY PREPARED:	November 15, 2004
TRADE OR PROPRIETARY DEVICE NAME:	Cabling System Trochanteric Hook
COMMON OR USUAL NAME:	Cabling System
CLASSIFICATION NAME:	Bone fixation cerclage. Single/multiple component metallic bone fixation appliances and accessories.
DEVICE CLASS:	Class II
PANEL CODE:	Orthopedic/87

DEVICE INFORMATION:

INTENDED USE:
Trochanteric reattachment whenever the trochanter is osteotomized in any of the procedures listed below.

1. Primary total hip arthroplasty
2. Revision total hip arthroplasty
3. Any procedure using anterolateral or lateral approaches

DEVICE DESCRIPTION:
The Cabling System Trochanteric Hook is made of Ti-6Al-4V. The trochanteric hook is used in conjunction with 2.0mm diameter cobalt chrome cables and cobalt chrome clamps from the Smith & Nephew Orthopaedics Cabling System (K031162). The trochanteric hook features one hook to attach to the trochanter and one hole to allow a cable to be routed through the device. The cable is routed through the hole in the device and around the femur. The cable will be tensioned and secured with a clamp. The hook is designed to prevent proximal migration of the trochanter. The device is intended for single use.

SUBSTANTIAL EQUIVALENCE INFORMATION:
The Cabling System Trochanteric Hook is similar to the Smith & Nephew Orthopaedic Cabling System Trochanteric Grip (K031162) in that both devices are used with the same cables and clamps for trochanteric reattachment whenever the trochanter is osteotomized. The grips in the predicate system feature two hooks to attach to the trochanter, multiple holes to allow cables to be routed through the grip and clamps to secure the cables. The Cabling System Trochanteric Hook features one hook to attach to the trochanter and one hole to allow a cable to be routed through the device and a clamp to secure the cable.

The Cabling System Trochanteric Hook is similar to the Howmedica Dall-Miles Cable Grip (K984432), Pioneer System Greater Trochanteric Reattachment Device (K961267) and the Biomet BMP Cable System (K982545) in that all devices are used with cables and clamps for trochanteric reattachment whenever the trochanter is osteotomized.

The Cabling System Trochanteric Hook is similar to the Smith & Nephew Hook Plate in that both devices are used for trochanteric reattachment whenever the trochanter is osteotomized. The trochanteric hook is used with cables and clamps to secure the device to the bone. The hook plate is used in conjunction with screws to secure the device to the bone.

The Cabling System Trochanteric Hook is substantially equivalent to the predicate devices. The differences between the Cabling System Trochanteric Hook and predicate devices do not affect safety and effectiveness.

SUMMARY OF TECHNOLOGICAL COMPARISON:

The Ilizarov Pulley System is substantially equivalent to the predicate devices listed in the previous section in terms of indications for use and design.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 14 2005

Mr. John Reabe
Director Regulatory Affairs
Smith & Nephew, Inc.
Orthopaedic Division
1450 Brooks Road
Memphis, Tennessee 38116

Re: K043252
Trade Name: Cabling System Trochanter Hook
Regulation Number: 21 CFR 888.3010
Regulation Name: Bone fixation cerclage
Regulatory Class: II
Product Code: JDQ
Dated: November 22, 2004
Received: November 23, 2004

Dear Mr. Reabe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K043252

Device Name: Cabling System Trochanteric Hook

Indications for Use:

Trochanteric reattachment whenever the trochanter is osteotomized in any of the procedures listed below.

1. Primary total hip arthroplasty
2. Revision total hip arthroplasty
3. Any procedure using anterolateral or lateral approaches

Prescription Use X (Per 21 CFR 801.109) OR Over-the-Counter Use _____ (Optional Format 1-2-96)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N Milhous

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K043252